NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of epiduroscopic lumbar discectomy through the sacral hiatus for sciatica

The tough covering of a spinal disc can sometimes tear, allowing the soft centre to bulge through. This is called herniation, also known as 'slipped disc'. It may cause pain in the back and leg (sciatica), and numbness and weakness in the leg. In this procedure the bulging part of the disc is removed using an endoscope (a thin, flexible tube with a camera on the end) and other instruments inserted through a small cut between the buttocks and up the spinal canal to the mid back. The aim is to relieve pain by removing parts of the disc that press against the spinal nerve.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in January 2016.

Procedure name

- Epiduroscopic lumbar discectomy through the sacral hiatus for sciatica

Specialist societies

- British Association of Spinal Surgeons

Description

Indications and current treatment

Lumbar disc herniation occurs when the nucleus pulposus of an intervertebral disc protrudes through a weakening or tear in the surrounding annulus fibrosus. Symptoms include pain in the back or leg, and numbness or weakness in the leg. Serious neurological sequelae including painful foot drop, bladder dysfunction, or cauda equina syndrome, may sometimes occur.

Conservative treatments include analgesics, non-steroidal anti-inflammatory medication and manual therapy. Epidural corticosteroid injections can also be used to reduce nerve pain in the short term. Lumbar discectomy is considered if there is severe nerve compression or persistent symptoms that are unresponsive to conservative treatment. Surgical techniques include open discectomy or minimally invasive alternatives using percutaneous endoscopic approaches. The choice of operative technique may be guided by several factors, including the presenting symptoms and signs and the location and size of the disc involved.

What the procedure involves

Epiduroscopic lumbar discectomy through the sacral hiatus for sciatica is usually done with the patient under sedation and local anaesthesia.

Under fluoroscopic guidance, a needle is inserted through the sacral hiatus. Over a guidewire a dilator is used to create a working channel through which a flexible endoscope can be steered into the anterior epidural space. The endoscope can reach nerve roots as high as the mid-lumbar lumbar spine bilaterally. When the appropriate disc level is reached, a laser optic fibre is introduced through the working channel of the endoscope to ablate disc tissue. The aim is to relieve pain by removing parts of the disc that press against the spinal nerve.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to epiduroscopic lumbar discectomy through the sacral hiatus for sciatica. The following databases were searched, covering the period from their start to 8 January 2016: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with sciatica.
Intervention/test	Epiduroscopic lumbar discectomy through the sacral hiatus
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on approximately 386 patients from 2 non-randomised comparative studies and 2 case series[1–4].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on epiduroscopic lumbar discectomy through the sacral hiatus for sciatica

Study 1 Kim JD (2011)

Details

Study type	**Non-randomised comparative study**
Country	Korea
Recruitment period	2008–11
Study population and number	Patients with lumbar spinal stenosis n=**98 patients (78 adhesiolysis, foraminoplasty + discectomy versus 20 adhesiolysis + foraminoplasty without discectomy)**
Age and sex	Mean age: adhesiolysis, foraminoplasty + discectomy group, 58.5 years; adhesiolysis + foraminoplasty without discectomy group, 65.6 years Sex: adhesiolysis, foraminoplasty + discectomy group, 51% (40/78) male; adhesiolysis + foraminoplasty without discectomy, 55% (11/20) male
Patient selection criteria	Inclusion criteria: patients with chronic low back pain and radiculopathy which failed to respond to at least 3 months of conservative treatments (epidural steroid injections or oral analgesia) were included. Exclusion criteria: patients with renal failure, chronic liver disease, calcification and adhesion inside the spinal canal due to chronic spinal stenosis, osseous lesions that resulted in degenerative conditions or patients who were pregnant were excluded.
Technique	All procedures were performed using local anaesthesia. Adhesiolysis, foraminoplasty + discectomy group: A flexible endoscope was inserted into the anterior and posterior epidural space through an incision in the sacral hiatus region. The endoscope was advanced to the site of stenosis, and then adhesiolysis and foraminoplasty were performed. Subsequently, a discectomy was performed using a Ho:YAG laser to cauterise and decompress the intervertebral disc nucleus. Adhesiolysis + foraminoplasty without discectomy group: no discectomy was performed following adhesiolysis and foraminoplasty.
Follow-up	**Adhesiolysis, foraminoplasty + discectomy group, mean of 20.7 months** **Adhesiolysis + foraminoplasty without discectomy group, mean of 23 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: No patients were lost to follow-up.

Study design issues: Study assessed the added benefit of performing endoscopic laser lumbar discectomy after adhesiolysis and foraminoplasty. All procedures were performed by 1 surgeon.

Study population issues: Diagnoses in the adhesiolysis, foraminoplasty + discectomy group included lumbar spinal stenosis, 53.8% (42/78); lumbar disc extrusion, 32.1% (25/78); postoperative pain after lumbar disc surgery, 10.3% (8/78); and chronic refractory low back pain caused by a lesion that was not identified before surgery, 3.8% (3/78). Diagnoses in the adhesiolysis + foraminoplasty without discectomy group included lumbar spinal stenosis, 90% (18/20); lumbar disc extrusion, 5% (1/20); and postoperative pain after lumbar disc surgery, 5% (1/20). Visual analogue scores for radicular pain ranged from 0–10 with lower scores indicating less pain. Roland Morris disability questionnaire scores ranged from 0–24 with lower scores indicating less disability. The Macnab classification system rates the results of spine surgery using a 4-point scale: excellent: no pain or restriction of activity; good: occasional back or leg pain of sufficient severity to interfere with the patients' ability to do normal work or capacity to enjoy themselves in leisure hours; fair: improved functional capacity, but handicapped by intermittent

pain of sufficient severity to curtail or modify work or leisure activities; poor: no improvement or insufficient improvement to enable an increase in activities; further operative intervention needed.

Other issues: there is an overlap in authorship between this study and Lee GW (2014) and there may be some overlap in patient populations.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **98 (78 adhesiolysis, foraminoplasty + discectomy versus 20 adhesiolysis + foraminoplasty without discectomy)**

Changes in outcome measures

		Mean score		
Outcome measure	Group	Baseline	1 month	Final follow-up
VAS score for pain	Discectomy	7.6	4.9	3.6
	Without discectomy	8.5	4.6	6.1
RMDQ score	Discectomy	18.8	11.4	10.6
	Without discectomy	11.3	9.6	11.4

- No p values were reported for analyses of changes within groups or comparisons between groups.

Postoperative outcomes at final follow-up according to Macnab criteria

	Proportion of patients: % (n/N)			
Group	Excellent	Good	Fair	poor
Discectomy	32 (25/78)	24 (19/78)	26 (20/78)	18 (14/78)
Without discectomy	15 (3/20)	10 (2/20)	20 (4/20)	55 (11/20)

Safety

Endoscopy-related adverse events (<u>in all patients</u>)

- Transient headaches were reported in 8% (8/98) of all patients included in the study.
- Focal infection was reported in 2% (2/98) of all patients included in the study.
- Transient hyperaesthesia was reported in 1 patient.
- Pain over the endoscope insertion site was reported in 1 patient
- Meningitis was reported in 1 patient. Symptoms resolved after bed rest and symptomatic treatment (undefined).

Laser-related adverse events (in the discectomy group)

- Foot drop was reported in 3% (2/78) of patients in the END + laser lumbar discectomy group. Symptoms resolved within 6 months.
- Paraesthesia was reported in 19% (15/78) of patients in the END + laser lumbar discectomy group. Symptoms resolved with 6 months.

Abbreviations used: RMDQ, Roland Morris disability questionnaire; VAS, visual analogue scale

Study 2 Lee GW (2014)

Details

Study type	**Non-randomised comparative study**
Country	Korea
Recruitment period	2008–12
Study population and number	Patients with lumbar spinal stenosis n=**57 patients (32 adhesiolysis, foraminoplasty + discectomy versus 25 adhesiolysis + foraminoplasty without discectomy)**
Age and sex	Mean age: adhesiolysis, foraminoplasty + discectomy group, 65.2 years; adhesiolysis + foraminoplasty without discectomy group, 67.1 years Sex: adhesiolysis, foraminoplasty + discectomy group, 47% male; adhesiolysis + foraminoplasty without discectomy group, 44% male
Patient selection criteria	Inclusion criteria: patients with central canal stenosis concurrently with or without foraminal stenosis because of hypertrophied ligamentum flavum, facet hypertrophy, and bony compression (such as bony spur), were included. All patients had low back pain, with or without sciatica, which failed to respond to 3 months of conservative treatment (including oral medication, physical therapy and unspecified injections). Exclusion criteria: patients with failed back surgery syndrome, spondylolysis or lumbar disc herniation without stenotic lesions were excluded.
Technique	All procedures were done using local anaesthesia. Adhesiolysis, foraminoplasty + discectomy group: A flexible endoscope was inserted into the anterior and posterior epidural space through an incision in the sacral hiatus region. The endoscope was advanced to the site of stenosis, and then adhesiolysis and foraminoplasty were performed. Subsequently, a discectomy was performed using a Ho:YAG laser to cauterise and decompress the intervertebral disc nucleus. Adhesiolysis + foraminoplasty without discectomy group: no discectomy was done after adhesiolysis and foraminoplasty.
Follow-up	**Minimum of 2 years**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: Authors state that 32 patients were enrolled in the adhesiolysis, foraminoplasty + discectomy group and 25 patients were enrolled in the adhesiolysis + foraminoplasty without discectomy group. They then report results for 27 patients in the adhesiolysis, foraminoplasty + discectomy group and 20 patients in the adhesiolysis + foraminoplasty without discectomy group but do not explicitly state that the missing patients were lost to follow-up.

Study design issues: Study assessed the added benefit of performing endoscopic laser lumbar discectomy after adhesiolysis and foraminoplasty. All procedures were performed by 1 surgeon.

Study population issues: There were various causes of lumbar spinal stenosis, including thickened ligament flavum, hypertrophic facet joints and herniated lumbar disc; however, authors did not state proportions in each group. Visual analogue scale (VAS) scores for back pain and VAS scores for radicular pain ranged from 0–10 with lower scores indicating less pain. Roland Morris disability questionnaire scores ranged from 0–24 with lower scores indicating less disability.

Other issues: there may be some patient population overlap with Kim JD (2011).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **47 (27 adhesiolysis, foraminoplasty + discectomy versus 20 adhesiolysis + foraminoplasty without discectomy)**

Clinical outcomes (mean±standard deviation)

Follow-up	Discectomy n=27	Without discectomy n=20	p value
VAS for low back pain			
Baseline	8.1±0.7	8.5±1.3	0.41
1 month	3.1±0.3	3.8±0.4	0.11
6 months	3.0±0.7	4.1±0.5	0.03
12 months	3.5±0.6	4.9±0.3	0.02
24 months	4.4±0.5	6.7±0.9	<0.01
	p=0.01*	p=0.12*	
VAS for leg pain			
Baseline	6.2±0.9	6.7±0.8	0.27
1 month	2.8±0.4	3.1±0.7	0.06
6 months	2.9±0.3	3.2±0.4	0.07
12 months	3.9±0.4	4.5±0.8	0.03
24 months	4.7±0.6	5.2±0.6	0.05
	p=0.07*	p=0.15*	
RMDQ scores			
Baseline	13.2±0.9	12.6±1.2	0.32
1 month	7.2±0.5	8.6±0.6	0.04
6 months	6.8±0.5	8.5±0.9	0.01
12 months	7.1±0.6	9.7±1.1	<0.01
24 months	8.5±0.3	10.4±0.5	<0.01
	p=0.03*	p=0.09*	

* baseline versus 24-month follow-up

Note: Where there are discrepancies in the numbers reported, data have been extracted from the tables of the article rather than the text.

Safety

Epiduroscopy-related adverse events (<u>in all patients, n=57</u>)

- Transient headaches were reported in 5% (3/57) of all patients included in the study.
- Focal infection of the entry site was reported in 4% (2/57) of all patients included in the study.
- Meningitis was reported in 1 patient. Symptoms resolved after bed rest and treatment with medication.

Laser-related adverse events (in the discectomy group)

- Transient mild motor paralysis was reported in 1 patient. Symptoms resolved within 1 month after the procedure.

Abbreviations used: RMDQ, Roland Morris disability questionnaire; VAS, visual analogue scale

Study 3 Richter (2011)

Details

Study type	**Case series**
Country	Multiple: United states, South Korea, Italy, Spain, Belgium and Mexico
Recruitment period	2009–11
Study population and number	Patients with low back pain with or without sciatica caused by 'discogenic pathology' (assumed to be disc herniation) n=**154 patients**
Age and sex	Not reported
Patient selection criteria	Inclusion criteria: patients with severe back pain with or without leg pain with radiculopathic features were included. All patients had symptoms that failed to respond to conservative treatment options (not specified).
Technique	All procedures were performed using local anaesthesia and with the patient under sedation. A flexible endoscope was inserted into the anterior epidural space through an incision in the sacral hiatus region. Following a laminotomy, the endoscope was advanced to the site of stenosis and a laser discectomy was performed.
Follow-up	**Not reported**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: Authors did not report whether there were any losses to follow-up.

Study design issues: Patients were recruited from 8 participating centres. The number of clinicians undertaking the procedures was not stated.

Study population issues: Demographic characteristics of the study population were not reported. Furthermore, authors did not report or stratify the types of discogenic pathology in the study population. Visual analogue scale (VAS) scores for pain ranged from 0–10 with lower scores indicating less pain. Roland Morris disability questionnaire scores ranged from 0–24 with lower scores indicating less disability.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **154** • VAS scores for pain scores decreased from 7.5±1.0 at baseline to 3.4±1.3 at follow-up (p<0.005). • Roland Morris disability questionnaire scores decreased from 18.1±4.0 at baseline to 10.3±3.8 at final follow-up (p<0.005). 82% of patients had a successful outcome at follow-up (based on the modified MacNab scale; 'excellent', 'very good' and 'good' categories were noted as 'successful', and 'poor' and 'terrible' were noted as 'failure').	• Study did not actively monitor the occurrence of adverse events.
Abbreviations used: VAS, visual analogue scale	

Study 4 Jo DH (2013)

Details

Study type	**Case series**
Country	Korea
Recruitment period	2011–12
Study population and number	Patients with refractory low back or lower extremity pain n=**77 patients**
Age and sex	Mean 58 years; 39% (30/77) male
Patient selection criteria	Inclusion criteria: patients with refractory low back or lower extremity pain, which did not improve with non-invasive conservative treatment including fluoroscopically-guided epidural steroid injection, or when 50% or more of the pain returned within 1 week.
Technique	Epiduroscopic laser neural decompression. Technique is not described in detail.
Follow-up	**1 month**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: 1 patient was lost to follow-up at 2 weeks and 3 patients were lost to follow-up at 1 month.

Study design issues: Retrospective review of medical records.

Study population issues: 4 patients had failed back surgery syndrome, 44 patients had lumbar disc herniation, 11 had lumbar spinal stenosis, 16 had lumbar disc herniation and lumbar spinal stenosis, and 2 patients had lumbar facet joint syndrome. Symptom duration was 5 years or more for 24 patients and between 1 and 5 years for 23 patients. The degree of pain relief was assessed on a 5-point scale: 1=very bad, 2=bad, 3=no change, 4=good, 5=very good. The baseline symptom scores were not reported.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>Number of patients analysed: 77

Symptom relief scores at follow-up % (n)
<table>
<tr><th></th><th>2-week follow-up (n=76)</th><th>1-month follow-up (n=74)</th></tr>
<tr><td>5 (very good)</td><td>42.1 (32)</td><td>10.8 (8)</td></tr>
<tr><td>4 (good)</td><td>46.1 (35)</td><td>74.3 (55)</td></tr>
<tr><td>3 (no change)</td><td>9.2 (7)</td><td>10.8 (8)</td></tr>
<tr><td>2 (bad)</td><td>2.6 (2)</td><td>1.4 (1)</td></tr>
<tr><td>1 (very bad)</td><td>0</td><td>2.7 (2)</td></tr>
</table>
81.8% (63/77) of patients had improved 1 month after the procedure.</td><td>The sutured area opened after removal of stitches from the operated area 1 week after the procedure in 1 patient.</td></tr>
</table>

Efficacy

Pain relief

A non-randomised comparative study of 98 patients compared treatment by endoscopic adhesiolysis, foraminoplasty and discectomy (n=78) with endoscopic adhesiolysis and foraminoplasty without discectomy (n=20). Visual analogue scale (VAS) scores for radicular pain (scores range from 0–10, with lower scores indicating less pain) improved from 7.6 to 3.6 with discectomy and from 8.5 to 6.1 without discectomy at final follow-up (p values not reported; mean follow-up periods were 21 and 23 months respectively)[1]. A non-randomised comparative study of 57 patients compared treatment by endoscopic adhesiolysis, foraminoplasty and discectomy (n=32) with endoscopic adhesiolysis and foraminoplasty without discectomy (n=25). The improvement in VAS score for low back pain (scores range from 0–10, with lower scores indicating less pain) was statistically significant with discectomy (from 8.1 to 4.4; p=0.01) but not without discectomy (from 8.5 to 6.7; p=0.12) at 24-month follow-up. The difference between the groups was statistically significant ($p<0.01$)[2]. In the same study, improvements in VAS scores for leg pain were not statistically significant (from 6.2 to 4.7; p=0.07 and from 6.7 to 5.2; p=0.15 respectively) at 24-month follow-up. The difference between the groups was statistically significant (p=0.05). In a case series of 154 patients, there was a statistically significant decrease in VAS scores for pain from 7.5 at baseline to 3.4 at follow-up ($p<0.005$)[3]. In a case series of 77 patients, 81.8% (63/77) of patients had improved symptoms at 1-month follow-up[4].

Functional capacity

In the non-randomised comparative study of 98 patients, Roland Morris disability questionnaire scores (scores range from 0–24, with lower scores indicating less disability) changed from 18.8 to 10.6 with discectomy and from 11.3 to 11.4 without discectomy at final follow-up (p values not reported; mean follow up periods were 21 and 23 months respectively)[2]. In the non-randomised comparative study of 57 patients, the change in Roland Morris disability questionnaire scores (scores range from 0–24, with lower scores indicating less disability) was statistically significant (from 13.2 to 8.5; p=0.03) with discectomy but not without discectomy (from 12.6 to 10.4; p=0.09) at 24-month follow-up. The difference between the groups was statistically significant ($p<0.01$)[2]. In the case series of 154 patients, the change in Roland Morris disability questionnaire scores was statistically significant, from 18.1 at baseline to 10.3 at follow-up ($p<0.005$)[3].

Safety

Transient paralysis

Transient mild motor paralysis was reported in 1 patient from the discectomy group (n=32) in a non-randomised comparative study of 57 patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy or endoscopic adhesiolysis and foraminoplasty without discectomy. Symptoms resolved 1 month after the procedure[2]. Foot drop was reported in 2% (2/78) of patients in the discectomy group in the non-randomised comparative study of 98 patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy (n=78) or endoscopic adhesiolysis and foraminoplasty without discectomy (n=20)[1]. Symptoms resolved within 6 months.

Dysaesthesia

Transient hyperaesthesia was reported in 1 patient in the non-randomised comparative study of 98 patients. The authors did not differentiate between the groups [1]. Paraesthesia was reported in 19% (15/78) of patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy in the same study; symptoms resolved within 6 months.

Transient headaches

Transient headaches were reported in 8% (8/98 and 5% (3/57) of patients in the 2 non-randomised comparative studies of patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy or endoscopic adhesiolysis and foraminoplasty without discectomy. The authors did not differentiate between the groups[1,2].

Focal infection

Focal infection was reported in 2% (2/98) and 4% (2/57) of patients in the 2 non-randomised comparative studies of patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy or endoscopic adhesiolysis and foraminoplasty without discectomy. The authors did not differentiate between the groups [1,2].

Meningitis

Meningitis was reported in 1 patient each in the 2 non-randomised comparative studies of patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy or endoscopic adhesiolysis and foraminoplasty without discectomy. The authors did not differentiate between the treatment groups. Symptoms resolved after bed rest and symptomatic treatment [1,2].

Validity and generalisability of the studies

- Most of the studies were done in Korea. The results from this population may not be generalisable to the UK population.

- There may be some patient overlap, particularly between the 2 non-randomised comparative studies[1,2].
- Two studies evaluated the efficacy of percutaneous endoscopic laser lumbar discectomy as an adjunct to adhesiolysis and foraminoplasty[1,2].
- One study specifically excluded patients with failed back surgery syndrome[2].
- Studies used a number of different subjective scales but few objective efficacy outcome measures were reported.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain. NICE interventional procedure guidance 545 (2016). Available from http://www.nice.org.uk/guidance/ipg545
- Percutaneous intradiscal electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica. NICE interventional procedure guidance 544 (2016). Available from http://www.nice.org.uk/guidance/ipg544
- Percutaneous coblation of the intervertebral disc for low back pain and sciatica. NICE interventional procedure guidance 543 (2016). Available from http://www.nice.org.uk/guidance/ipg543
- Insertion of an annular disc implant at lumbar discectomy. NICE interventional procedure guidance 506 (2014). Available from http://www.nice.org.uk/guidance/ipg506
- Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010). Available from http://www.nice.org.uk/guidance/ipg357

- Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009). Available from http://www.nice.org.uk/guidance/ipg306
- Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009). This guidance is currently under review and is expected to be updated in 2016. For more information, see http://www.nice.org.uk/guidance/ipg300
- Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005). Available from http://www.nice.org.uk/guidance/ipg141
- Percutaneous endoscopic laser thoracic discectomy. NICE interventional procedure guidance 61 (2004) Available from http://www.nice.org.uk/guidance/ipg61
- Endoscopic laser foraminoplasty. NICE interventional procedure guidance 31 (2003). Available from http://www.nice.org.uk/guidance/ipg31

NICE guidelines

- Low back pain in adults: early management. NICE guideline 88 (2009). This guidance is currently under review and is expected to be updated in 2016. For more information, see http://www.nice.org.uk/guidance/cg88

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Three Specialist Advisor Questionnaires for epiduroscopic lumbar discectomy through the sacral hiatus for sciatica were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

None other than those described above.

References

1. Kim JD, Jang JH, Jung GH et al. (2011) Epiduroscopic laser disc and neural decompression. Journal of neurosurgical review supplement 1: 14-19
2. Lee GW, Jang SJ, Kim JD (2014) The efficacy of epiduroscopic neural decompression with Ho:YAG laser ablation in lumbar spinal stenosis. Eur J Orthop Surg Traumatol. Suppl 1:S231-7. doi: 10.1007/s00590-013-1407-7.
3. Richter EO, Abramova MV, Cantu F et al. (2011) Anterior epiduroscopic neural decompression: Eight-center experience in 154 patients. European Journal of Pain 5: 401-407
4. Jo DH, Yang HJ (2013) The survey of the patient received the epiduroscopic laser neural decompression. Korean Journal of Pain 26: 27–31

Appendix A: Additional papers on epiduroscopic lumbar discectomy through the sacral hiatus for sciatica

No additional papers were identified.

Appendix B: Related NICE guidance for epiduroscopic lumbar discectomy through the sacral hiatus for sciatica

Guidance	Recommendations
Interventional procedures	**Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain. NICE interventional procedure guidance 545 (2016)** 1.1 Current evidence on percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain raises no major safety concerns. The evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to do percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain should: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In particular, patients should be informed about other treatment options, about the possibility that the procedure may not relieve their symptoms, and about the risk of a flare-up of their pain after treatment. In addition, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain (see section 7.2). 1.3 NICE encourages further research into percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain. Further research should include details of patient selection, the duration of patients' symptoms, and a precise account of the technique used for treatment. Outcome measures should include pain relief and quality of life. Long-term follow-up data should include details of any subsequent procedures. **Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica. NICE interventional procedure guidance 544 (2016)** 1.1 Current evidence on percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is inconsistent and of poor quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to do percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica should:

	• Inform the clinical governance leads in their NHS trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In particular, patients should be informed about other treatment options, about the possibility that the procedure may not relieve their symptoms, and about the risk of a flare-up of their pain following treatment. In addition, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency treatment of the intervertebral disc annulus (see section 7.2). 1.3 NICE encourages further research into percutaneous electrothermal treatment of the intervertebral disc annulus. Further research should document details of patient selection, including the duration of their symptoms. It should report precise details of the technique used for treatment. Outcome measures should include pain relief and quality of life. Long-term follow-up data should include details of any subsequent procedures. **Percutaneous coblation of the intervertebral disc for low back pain and sciatica. NICE interventional procedure guidance 543 (2016)** 1.1 Current evidence on percutaneous coblation of the intervertebral disc for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is adequate and includes large numbers of patients with appropriate follow-up periods. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 As part of the consent process, patients should be informed that there is a range of treatment options available to them and also that further procedures may be needed. **Insertion of an annular disc implant at lumbar discectomy. NICE interventional procedure guidance 506 (2014)** 1.1 Current evidence on the safety and efficacy of insertion of an annular disc implant at lumbar discectomy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake insertion of an annular disc implant at lumbar discectomy should take the following actions: Inform the clinical governance leads in their NHS trusts. Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written

	information. In addition, the use of NICE's information for the public is recommended. 1.3 NICE encourages further research on insertion of an annular disc implant at lumbar discectomy, particularly comparative trials. All studies should report details of patient selection and recurrence rates. 1.4 Clinicians should enter details about all patients undergoing insertion of an annular disc implant at lumbar discectomy onto the British Spine Registry and review clinical outcomes locally. **Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010)** 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal laser ablation in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patients selected for the procedure should be limited to those with severe pain refractory to conservative treatment, in whom imaging studies show bulging of an intact disc, and who do not have neurological deficit requiring surgical decompression. **Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009)** 1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 A multidisciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated. 1.3 The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery. **Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009) (Current guidance)** 1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

	1.2 Clinicians wishing to undertake percutaneous endoscopic laser lumbar discectomy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having percutaneous endoscopic laser lumbar discectomy (see section 3.1). 1.3 Surgeons undertaking this procedure should have specific training in the use of lasers and in endoscopy of the spinal canal. 1.4 NICE encourages further research into percutaneous endoscopic laser lumbar discectomy and may review the procedure on publication of further evidence. Research studies should provide long-term outcome data. **Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005)** 1.1 Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having automated mechanical percutaneous lumbar discectomy. The Institute may review the procedure upon publication of further evidence. **Percutaneous endoscopic laser thoracic discectomy. NICE interventional procedure guidance 61 (2004)** 1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser thoracic discectomy does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

	1.2 Clinicians wishing to undertake percutaneous endoscopic laser thoracic discectomy should take the following action. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having percutaneous endoscopic laser thoracic discectomy. 1.3 Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence. **Endoscopic laser foraminoplasty. NICE interventional procedure guidance 31 (2003)** 1.1 Current evidence of the safety and efficacy of endoscopic laser foraminoplasty does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake endoscopic laser foraminoplasty should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's information for the public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Further research into safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.
NICE guidelines	**Low back pain in adults: early management. NICE guideline 88 (2009). This guideline is currently being updated.** **1.1 Assessment and imaging** 1.1.1 Keep diagnosis under review. 1.1.2 Do not offer X-ray of the lumbar spine for the management of non-specific low back pain. 1.1.3 Consider MRI (magnetic resonance imaging) when a diagnosis of spinal malignancy, infection, fracture, cauda equina syndrome or ankylosing spondylitis or another inflammatory disorder is suspected. 1.1.4 Only offer an MRI scan for non-specific low back pain within the context of a referral for an opinion on spinal fusion (see section 1.9). **1.2 Information, education and patient preferences** 1.2.1 Provide people with advice and information to promote self-management of their low back pain.

	1.2.2 Offer educational advice that: • includes information on the nature of non-specific low back pain • encourages the person to be physically active and continue with normal activities as far as possible. 1.2.3 Include an educational component consistent with this guideline as part of other interventions, but do not offer stand-alone formal education programmes. 1.2.4 Take into account the person's expectations and preferences when considering recommended treatments, but do not use their expectations and preferences to predict their response to treatments. 1.2.5 Offer one of the following treatment options, taking into account patient preference: an exercise programme (see section 1.3.3), a course of manual therapy (see section 1.4.1) or a course of acupuncture (see section 1.6.1). Consider offering another of these options if the chosen treatment does not result in satisfactory improvement. **1.3 Physical activity and exercise** 1.3.1 Advise people with low back pain that staying physically active is likely to be beneficial. 1.3.2 Advise people with low back pain to exercise. 1.3.3 Consider offering a structured exercise programme tailored to the person: • This should comprise up to a maximum of eight sessions over a period of up to 12 weeks. • Offer a group supervised exercise programme, in a group of up to 10 people. • A one-to-one supervised exercise programme may be offered if a group programme is not suitable for a particular person. 1.3.4 Exercise programmes may include the following elements: • aerobic activity • movement instruction • muscle strengthening • postural control • stretching. **1.4 Manual therapy** The manual therapies reviewed were spinal manipulation (a low-amplitude, high-velocity movement at the limit of joint range that takes the joint beyond the passive range of movement), spinal mobilisation (joint movement within the normal range of motion) and massage (manual manipulation or mobilisation of soft tissues). Collectively these are all manual therapy. Mobilisation and massage are performed by a wide variety of practitioners. Manipulation can be performed by chiropractors and osteopaths, as well as by doctors and

	physiotherapists who have undergone specialist postgraduate training in manipulation. 1.4.1 Consider offering a course of manual therapy, including spinal manipulation, comprising up to a maximum of nine sessions over a period of up to 12 weeks. **1.5 Other non-pharmacological therapies** *Electrotherapy modalities* 1.5.1 Do not offer laser therapy. 1.5.2 Do not offer interferential therapy. 1.5.3 Do not offer therapeutic ultrasound. *Transcutaneous nerve stimulation* 1.5.4 Do not offer transcutaneous electrical nerve simulation (TENS). *Lumbar supports* 1.5.5 Do not offer lumbar supports. *Traction* 1.5.6 Do not offer traction. **1.6 Invasive procedures** 1.6.1 Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks. 1.6.2 Do not offer injections of therapeutic substances into the back for non-specific low back pain. **1.7 Combined physical and psychological treatment programme** 1.7.1 Consider referral for a combined physical and psychological treatment programme, comprising around 100 hours over a maximum of 8 weeks, for people who: • have received at least one less intensive treatment (see section 1.2.5) and • have high disability and/or significant psychological distress. 1.7.2 Combined physical and psychological treatment programmes should include a cognitive behavioural approach and exercise. **1.8 Pharmacological therapies** Both weak opioids and strong opioids are discussed in the recommendations in this section. Examples of weak opioids are codeine and dihydrocodeine (these are sometimes combined with paracetamol as co-codamol or co-dydramol, respectively). Examples of strong opioids are buprenorphine, diamorphine, fentanyl and oxycodone. Some opioids, such as tramadol, are difficult to classify because they can act like a weak or strong opioid depending on the dose used and the circumstances.

	No opioids, cyclooxygenase 2 (COX-2) inhibitors or tricyclic antidepressants and only some non-steroidal anti-inflammatory drugs (NSAIDs) have a UK marketing authorisation for treating low back pain. If a drug without a marketing authorisation for this indication is prescribed, informed consent should be obtained and documented. 1.8.1 Advise the person to take regular paracetamol as the first medication option. 1.8.2 When paracetamol alone provides insufficient pain relief, offer: • non-steroidal anti-inflammatory drugs (NSAIDs) and/or • weak opioids Take into account the individual risk of side effects and patient preference. 1.8.3 Give due consideration to the risk of side effects from NSAIDs, especially in: • older people • other people at increased risk of experiencing side effects. 1.8.4 When offering treatment with an oral NSAID/COX-2 (cyclooxygenase 2) inhibitor, the first choice should be either a standard NSAID or a COX-2 inhibitor. In either case, for people over 45 these should be co-prescribed with a PPI (proton pump inhibitor), choosing the one with the lowest acquisition cost. [This recommendation is adapted from 'Osteoarthritis: the care and management of osteoarthritis in adults' (NICE clinical guideline 59).] 1.8.5 Consider offering tricyclic antidepressants if other medications provide insufficient pain relief. Start at a low dosage and increase up to the maximum antidepressant dosage until therapeutic effect is achieved or unacceptable side effects prevent further increase. 1.8.6 Consider offering strong opioids for short-term use to people in severe pain. 1.8.7 Consider referral for specialist assessment for people who may require prolonged use of strong opioids. 1.8.8 Give due consideration to the risk of opioid dependence and side effects for both strong and weak opioids. 1.8.9 Base decisions on continuation of medications on individual response. 1.8.10 Do not offer selective serotonin reuptake inhibitors (SSRIs) for treating pain. **1.9 Referral for surgery** 1.9.1 Consider referral for an opinion on spinal fusion for people who: • have completed an optimal package of care, including a combined physical and psychological treatment programme (see section 1.7) and • still have severe non-specific low back pain for which they would

	consider surgery. 1.9.2 Offer anyone with psychological distress appropriate treatment for this before referral for an opinion on spinal fusion. 1.9.3 Refer the patient to a specialist spinal surgical service if spinal fusion is being considered. Give due consideration to the possible risks for that patient. 1.9.4 Do not refer people for any of the following procedures: • intradiscal electrothermal therapy (IDET) • percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) • radiofrequency facet joint denervation.

Appendix C: Literature search for epiduroscopic lumbar discectomy through the sacral hiatus for sciatica

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	08/01/2016	Issue 1 of 12, January 2016
HTA database (Cochrane)	08/01/2016	Issue 4 of 4, October 2015
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	08/01/2016	Issue 12 of 12, December 2015
MEDLINE (Ovid)	08/01/2016	1946 to November week 3 2015
MEDLINE In-Process (Ovid)	08/01/2016	January 07, 2016
EMBASE (Ovid)	08/01/2016	1974 to 2016 Week 01
PubMed	08/01/2016	n/a
BLIC (British Library)	08/01/2016	n/a

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 epiduroscop*.tw. (63)
2 (epidural* adj4 (endoscop* or myeloscop*)).tw. (46)
3 (ELND or (epiduroscop* adj4 laser* adj4 neural* adj4 decompress*)).tw. (109)
4 (flex* adj4 endoscop*).tw. (2127)
5 (sacral* adj4 (hiatus* or vertebra* or canal*)).tw. (819)
6 ((trans* adj4 sacral*) or trans-sacral*).tw. (406)
7 or/1-6 (3513)
8 Low Back Pain/ (15837)
9 (low* adj4 (backpain* or back pain* or backache* or back ache*)).tw. (18606)
10 LBP.tw. (4320)
11 lumbago*.tw. (1093)
12 Sciatica/ (4451)
13 sciatic*.tw. (22474)
14 (chronic* adj4 back pain*).tw. (5601)
15 ((low* extremity or leg*) adj4 (weak* or pain* or ache* or discomfort*)).tw. (8270)

16	((displac* or degenerat* or degrad* or deteriorat* or decay* or slip* or extru* or hernia* or prolaps* or protru* or compress* or an?ulus or bulg*) adj4 (disc* or disk*)).tw. (22198)
17	((discogenic* or diskogenic* or radicular or non-dermatomal) adj4 pain*).tw. (2695)
18	Radiculopathy/ (3958)
19	(lumbar adj4 radiculopath*).tw. (584)
20	(nerv* adj4 root* adj4 imping*).tw. (98)
21	(cauda adj4 equina adj4 syndrome*).tw. (1085)
22	paraparesis/ (643)
23	paraparesis.tw. (4700)
24	(spinal adj4 fibrosis).tw. (80)
25	or/8-24 (83743)
26	7 and 25 (231)